UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GREGORY W. BARAN, M.D.,	)	
	)	
Plaintiff,	)	Civil Action No.: 1:04CV1251
	)	
vs.	)	Judge O'Malley
	)	
MEDICAL DEVICE TECHNOLOGIES, INC.,	)	Mag. Judge Baughman
	)	
	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANT MEDICAL DEVICE TECHNOLOGIES, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

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INTRODUCTION

Plaintiff, Gregory W. Baran, M.D. ("Baran") originally claimed that the BioPince® Full Core Biopsy Instrument (the "BioPince" or "accused device") that is now manufactured, distributed and sold by Medical Device Technologies, Inc. ("MDTech") infringed both claim 2 of U.S. Patent No. 5,400,798 (the "'798 patent") and claim 7 of U.S. Patent No. 5,025,797 (the "'797 patent"). In light of this Court's claim interpretation ruling following the *Markman* hearing, (Opinion & Order dated September 25, 2007, Docket Entry No. 132, hereinafter the "Order"), however, Baran was forced to admit that unless this Court's ruling is overturned, he cannot prove infringement under any claim of the '798 patent. (*See* Stipulation of the Parties with Respect to Claim 2 of the '798 Patent, Docket Entry No. 145, ¶ 2.) Now that discovery is closed as to issues of liability, and the parties' respective experts have submitted reports and been deposed, it is equally clear that Baran cannot meet his burden of proving, by a preponderance of evidence, that each limitation of claim 7 of the '797 patent reads on the accused device. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005); *see also Deering Precision Instruments LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003).

While the parties argue whether three of the nine limitations of claim 7 of the '797 patent are met in the BioPince device, there are no material factual disputes that prevent the entry of judgment of noninfringement in favor of MDTech at this time. Baran's expert, John R. Haaga, M.D. ("Haaga") and MDTech's expert, Majid Rashidi, Ph.D., P.E. ("Rashidi") agree on the following basic facts:

1.) Both parties agree that the accused device is an automatic, single use biopsy instrument, meaning it can only be used to take tissue samples from a single patient. (Exhibit 1, Affidavit of Monica L. Thompson, Exhibit A ("Ex. 1-A"), MDTech's designations from the transcript of the November 13, 2008

deposition of Haaga, ("Haaga Dep.") 124:1-12[1] and Ex. 1-B, MDTech's designations from the transcript of the November 19, 2008 deposition of Rashidi ("Rashidi Dep.") 110:14-111:20.)[2];

2.) While witnesses may disagree in the way they state their conclusions, both experts agree that the accused device does not contain a release lever that further includes a latching projection, a finger rest, and a mounting section such as that identified by the Court as the "release means for retaining the guide in a charged position." (*See* Ex. 1-A, Haaga Dep. 196:4-18 and 187:14-21 (agreeing that the release structure that he identified in the accused device is not a lever and does not include a finger rest) and Ex. 1-B Rashidi Dep. 267:3-15 (describing the release means identified by Haaga as a cantilever and agreeing that it does not have a finger rest).);

3.) Both experts agree that the BioPince uses a mechanism to charge the instrument, as opposed to a member configured to move the guide against the urging of a spring. (*See* Ex. 1-A, Haaga Dep. 171:8-19 (the cocking arm of the accused device "transmits force in a dynamic process of a mechanism") and Ex. 1-B, Rashidi Dep. 163:16-165:22 (describing the accused device's slider crank mechanism).); and ,

4.) Both experts agree that there is nothing but adhesive to bond the cannula to its guide, though they dispute whether this adhesive constitutes a "structure," such as the Court determined was inherent in the limitation of a "cannula mount." (Ex. 1-A Haaga Dep. 133:15-17 and Ex. 1-B Rashidi Dep. 159:16-160:24.)

The basic facts, therefore, are not in dispute and, for the reasons set forth below, summary judgment in favor of MDTech is appropriate at this time.

I. FACTUAL BACKGROUND

While this case does not involve any process for the taking of a biopsy, nor does it concern itself with the size or design of the needle set that is used obtain a sample, or the size or the quality of samples obtained, it nonetheless provides a helpful context for the arguments

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[1] The following citation form will be used for all affidavits and accompanying exhibits: "Ex. [No.]-[Letter and abbreviated name of attached exhibit with pin point citations as appropriate]."

[2] Exs. 1-E and 1-F, are DVD recordings with synchronized transcription of the depositions of Haaga and Rashidi, respectively, and Exs. 1-I and 1-J, are annotated examples of the accused devices, which are marked and will be delivered to the Court's Chambers before the conclusion of the briefing. Further, before the conclusion of the briefing, counsel will resubmit the deposition DVD recordings with only the designated portions corresponding to the hard copy designations included.

below to understand the clinical use of the accused device. An animated depiction of the BioPince in operation produced as marketing material by MDTech is provided as Exhibit 2, Affidavit of Sophie Marcoux ("Ex. 2") Exhibit H, demonstration DVD entitled "BioPince Full Core Biopsy Instrument," and is offered as a demonstrative exhibit with respect to the operation of the device and as evidence with respect to how MDTech instructs users to operate the device.

An overview of the invention is stated in the Order at 14-16.

The following verbal description of the relevant portions of the accused device is taken from the Expert Report of Majid Rashidi, Ph.D., P.E. ("Rashidi Expert Report"). (Exhibit 3-A Affidavit of Majid Rashidi, Ph.D., P.E.) The accused device has a three piece needle set for obtaining samples. This includes an inner Cannula (10) (sometimes referred to as the cutting Cannula) which is positioned inside an Outer Tube (12) (sometimes referred to as the pincer cannula), which contains a tapered pincer portion for cutting and retaining the sample. (*Id*. 4, 9.) A Stylet (20) is disposed within the cutting Cannula. (*Id.* 4) The cutting Cannula and pincer Outer Tube are attached to interlocking Guides. (*Id*.) The cutting Cannula is positioned in a V-shaped trough on the Back Guide (16) and is permanently held in place by adhesive. (*Id*.) The Outer Tube is positioned in a V-shaped trough on the Front Guide (18) and is likewise permanently held in place by adhesive. (*Id*.) The Front Guide and the Back Guide are connected in such a way that they can move together when being placed in a charged position, as well as during the first part of the spring-propelled discharge, but they can also move separately during the final stage of the discharge stroke. (*Id*.) The Stylet has a region near its proximal end that is permanently and directly attached to the Stylet Retaining Block (22). (*Id.*) The entire needle set is enclosed in a generally hollow rectangular Housing (24). (*Id*.) The Guides can slide within the Housing, subject to the resistance of a Spring (26). (*Id.*)

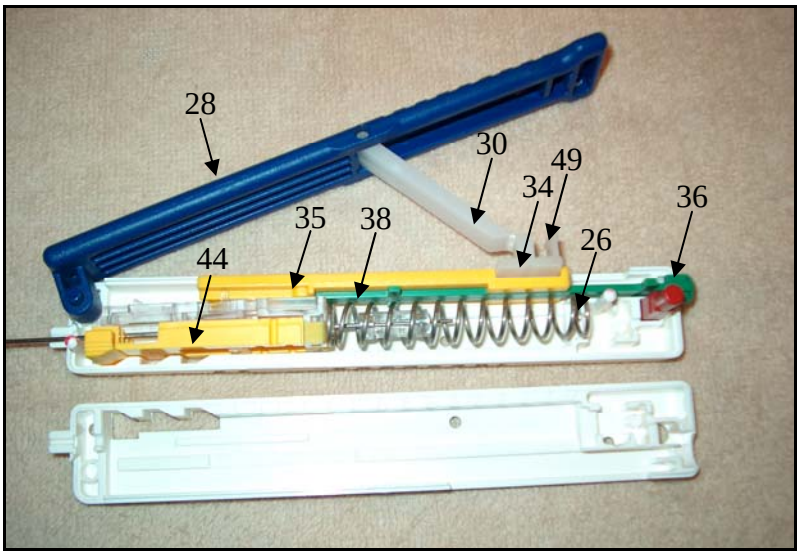

Figure 1 – The accused device with the Housing opened to show the internal parts.

The accused device includes a slider-crank mechanism for charging the device, which includes a Crank Arm (28), a Connecting Rod (30), and a Slider Link (35). (Ex. 1-B, Rashidi Dep. 164:15-165:2; Ex. 3-A, Rashidi Expert Report 9-15.) The Crank Arm is pivotally connected to the Connecting Rod (30) which is connected by the Living Hinge (32) to the Crank Arm Fixer (34). (Ex. 3-A, Rashidi Expert Report 13.) In order to charge the instrument, the user holds the Housing with one hand and lifts the Crank Arm with the other hand until the Locking Groove (46) snaps over the Latching Protrusion (48) of the Front Guide. (Ex. 3-A, Rashidi Report 13-14) The Crank Arm is then depressed toward the Housing. (*Id.* 14.) This action forces the Connecting Rod to push Crank Arm Fixer to proximal end of the Housing. (*Id.*) Because the Slider Link is engaged with the Front Guide, both Guides are moved toward the proximal end of the Housing and the Spring (26) is compressed between the Back Guide and the Housing. (*Id.*) When the Crank Arm reaches the Housing, the Crank Arm Locking Tab (49) inserts through the opening in the Crank Arm and engages the lip of the opening, thereby locking

the Crank Arm in place. (Ex. 1-B, Rashidi Dep. 239:11-15.) The instrument is charged; the Stylet is exposed. (*See* Ex. 1-A, Haaga Dep. 151:14-17.)

A Trigger Button (36) is the proximal end of an Elongated Release Bar (38), which is disposed between the Slider Link and the Guides. (Ex. 3-A, Rashidi Expert Report 13.) To fire, the instrument, a user depresses the Trigger Button (*Id.* 14-15), which urges the Elongated Release Bar forward, causing it to wedge between the Latching Protrusion of the Front Guide and the Locking Groove of the Slider Link until they disengage. (*Id.* 15.) Once the Latching Projection is disengaged from the Locking Groove, the compressed Spring is released and it consequently propels the Guides forward. The distal end of the cutting Cannula advances into the tissue to be sampled. (*Id.*) When the Back Guide contacts a Guide Stop (44), the forward progress of the cutting Cannula is arrested, however, the momentum of the Front Guide causes it to advance an additional few millimeters. (*Id.*) This slight forward movement allows the pincer of the Outer Tube to enter into a bore in the cutting Cannula slicing off the tissue sample and allowing a full core to be extracted. (*Id.*)

II. LEGAL STANDARDS

A. LEGAL STANDARD FOR SUMMARY DETERMINATION

Summary judgment is appropriate where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(b). Literal infringement is a question of fact and may be decided on summary judgment when no genuine issue of material fact exists, such that no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device. *Sentry Protection Prods., Inc. v. Eagle Mfg. Co.*, No. 1:01 CV 2240, 2003 WL 25539702, at *17 (N.D. Ohio Sept.

30, 2003) (citing *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998))[3]. Similarly, summary judgment is appropriate notwithstanding a claim of infringement under the doctrine of equivalents where the evidence is such that no reasonable jury could determine two elements to be equivalent. *Alpha Enters., Inc. v. Tomato Land Display Sys., Inc.*, 92 F. Supp. 2d 733, 736-37 (S.D. Ohio 2000) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 38 n.8, 117 S. Ct. 1040 (1997)).

Summary judgment of noninfringement is required where even one limitation is not present. *See Bai*, 160 F.3d at 1353. A party opposing summary judgment must produce admissible evidence, such as a detailed affidavit from a knowledgeable person, supporting material facts that the party claims are in dispute. "Mere denials or conclusory statements are insufficient." *Hargabus v. Cedar Fair, L.P.*, No. 1:04CV1751, 2005 WL 2233248, at *11 (N.D. Ohio Sept. 14, 2005) (citing *TechSearch L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002)).

B. LEGAL STANDARD FOR PERSON HAVING LEVEL OF ORDINARY SKILL IN THE ART

The determination of whether the accused device includes each of the limitations of a patent's claim is made from the vantage of the person having ordinary skill in the art. The person having ordinary skill in the art is that hypothetical person who is presumed to be aware of all the pertinent prior art. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). "Generally, the skill is that of a person who would be expected to solve the type of problem in question rather than that of a person who ordinarily uses the product or process." 1 Donald S. Chisum, *Chisum on Patents*, Glossary, at G1-12 (2008).

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[3] Cases for which only Westlaw citation is available are attached as Exhibit 4.

The issues in this case involve the mechanical operation of an automated device that uses the energy of a compressed spring to drive one or more telescopically disposed cannulas over a stylet into the mass from which the physician, the end user, desires to obtain a sample. The end user, who may be highly skilled in minimally invasive medical procedures does not necessarily have any understanding of the design of the charging or firing mechanism that drives the automated portions of the needle set. Dr. Rashidi, however, who understands the use of stored kinetic energy, is imminently qualified to speak as a person skilled in the relevant art. In addition to his engineering and product design expertise, he has taught biomechnical engineering courses and has invented commercially viable medical and medical related devices. (*See* Ex. 1-B, Rashidi Dep. 20:10-15, 18:22-19:3, 255:12-15, 41:6-18, Ex. 3-A, Rashidi Expert Report Exhibit 1 (discussing his experience designing medical devices, courses he taught, and medical devices he developed and sold).) Rashidi is the only witness who has offered testimony that not only describes the specific operations of the device, but who can also relate them to commonly used engineering principals. As a result, he authored his own report in which he described and compared the relative effort required to operate the accused device and the patented invention, demonstrating the significant differences between the two designs and the reasons why the patent claims do not read on the accused device. (Ex. 1-B, Rashidi Dep. 94:25-95:25 and 96:9-17.)

By comparison, the testimony offered by Haaga is that of a knowledgeable doctor, who has a lay person's understanding of the reasons why the devices operate as they do. He needed significant assistance in authoring his report and admits that much of it was provided by the lawyers as he did not fully understand the terms that were used. (*See* Ex. 1-A, Haaga Dep. 74:4-18, 76:10-16, 77:25-79:6, 94:12-95:19, 113:17-22, 128:5-18, and 172:15-22 (admitting the discussions of the limitations and drawings depicting the accused device were predominately

drafted by counsel and that he uses terms in his report which he does not understand, such as a claim "limitation," and that he has only a layman's understanding of terms such as "equivalents").)

C. LEGAL STANDARD FOR LITERAL INFRINGEMENT

To determine whether literal infringement has occurred, the Federal Circuit applies a two-step analysis. Once the claims have been correctly construed to determine their scope, the claims must be compared to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). To find literal infringement, each limitation of the claim must be present in the accused device. Any deviation from the claim precludes such a finding. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996).

One of the limitations in this case is written as a "means plus function." The Federal Circuit's two-step analysis of a means-plus-function claim begins with identification of the claim function. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001). When identifying the claim function, courts must apply the ordinary principles of claim construction to construe the function of the means-plus-function limitation to include the limitations contained in the claim language, and only those limitations. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc*, 296 F.3d 1106, 1113 (Fed. Cir. 2002) (citation omitted). The second step requires identification of the structures disclosed in the specification and equivalents thereof that perform the claimed function. *Telemac*, 247 F.3d at 1324 (citation omitted). To find that the limitation is present in the accused product for an infringement analysis, "the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for that structure." *Minks v. Polaris Indus., Inc.*, 546 F.3d

1364, 1378 (Fed. Cir. 2008) (internal quotations omitted) (citing *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998)).

D. LEGAL STANDARD FOR INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

Under the doctrine of equivalents, a claim limitation not literally met may be satisfied by an element of the accused device if the differences between the two are "insubstantial" to one of ordinary skill in the art. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003) (citing *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S. Ct. 1040 (1997)). The "insubstantial differences inquiry" may be guided by determining whether the element in the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the claim limitation. *Boehringer*, 320 F.3d at 1351 (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854 (1950)).

To prove infringement under the doctrine of equivalents, the Federal Circuit has held that a patentee must present "particularized testimony and linking argument" demonstrating insubstantial differences between the accused device and each claim limitation. *Lear Siegler, Inc. v. Sealy Mattress Co. of Mich., Inc.*, 873 F.2d 1422, 1426 (Fed. Cir. 1989). To satisfy this burden, a patentee must do more than identify the respective function, way, and result of the accused device and the claim limitation; rather, a patentee must provide analysis explaining why the function, way, and result of the accused device and the claim limitation are the same. *See Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991) (noting that the Federal Circuit "at least requires the *evidence* to establish *what* the function, way, and result of *both* the claimed device and the accused device are, and *why* those functions, ways and results are substantially the same") (emphasis in original); *see also Lear Siegler*, 873 F.2d at 1425 ("The

evidence and argument on the doctrine of equivalents cannot merely be subsumed in plaintiff's case of literal infringement.").

Equivalents of means-plus-function claims are not coextensive with the doctrine of equivalents. *Chiuminatta*, 145 F.3d at 1310. Once the relevant structure in the accused device has been identified, a party may prove it is equivalent to the disclosed structure by showing that the two perform the "***identical*** function" in substantially the same way, with substantially the same result. *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 (Fed. Cir. 2006) (emphasis added).

E. BARAN'S EXPERT CANNOT RAISE A TRIABLE ISSUE OF INFRINGEMENT BY MERELY RECITING THE TERM "EQUIVALENTS."

Haaga freely admitted that he did not understand the legal meaning of the term "equivalents" as used in an infringement analysis. (Ex. 1-A, Haaga Dep. 76:10-16.) In his repeated attempts to deal with this term, he never got past the simple observation that the accused device and the claimed invention ultimately did the same thing. (*Id.* 76:17-78:14 (discussing his "[un]sophisticated interpretation" of the doctrine of equivalents and his analysis that focuses on whether the outcome of the devices are similar).) The Haaga Report is devoid of any analysis of the alleged "equivalence," except for Haaga's bald recitation of the term "equivalent structure." (Ex. 1-C, Export Report of John R. Haaga, M.D. ("Haaga Expert Report") 22.)

The Federal Circuit has made clear that a claim of infringement under the doctrine of equivalents cannot be preserved merely by reciting the term "equivalent" or the like. *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1210 (Fed. Cir. 2001) ("The doctrine of equivalents is not a talisman that entitles a patentee to a jury trial on the basis of suspicion; it is a limited

remedy available in special circumstances, the evidence for which is the responsibility of the proponent."). Most importantly, "generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice." *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1305 (2007) (citing *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)). And, the same rule applies in the summary judgment context. *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1363 (Fed. Cir. 2005) (citing *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005)).

III. ARGUMENT

To prevail on his infringement claim, Baran must prove that the accused device has each of the following limitations:

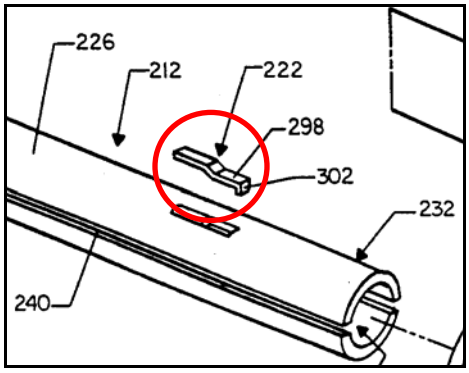
> 7. A biopsy instrument comprising an elongate hollow casing, a needle extending outwardly from the casing and having a cannula and a stylet received within the cannula, a stationary support mounted within the casing in fixed relation thereto and having means affixing the stylet thereto, a cannula guide, **a cannula mount affixing the cannula to the guide,** the guide being completely enclosed by the casing for reciprocating movement therewithin relative to the stationary support between a charged position, wherein the cannula is retracted in a direction away from the distal end of the stylet, and a discharged position, wherein the cannula is displaced from the charged position in the direction of the distal end of the stylet, a coil spring engaged between the stationary support and the guide for urging the guide toward the discharged position, **a manually operable charging member for moving the guide to the charged position against the urging of the coil spring,** and **a release means for retaining the guide in the charged position.**

(Ex. 1-D, the '797 patent, col. 12:54-13:5; Order 16.)

The accused device does not infringe the '797 patent because it does not include at least three of the limitations set out in bold above.

A. THE ACCUSED DEVICE DOES NOT INCLUDE A RELEASE MEANS THAT ALSO RETAINS THE GUIDE IN THE CHARGED POSITION

The Court and the parties all agreed at the *Markman* hearing that the "release means for retaining the guide in the charged position . . . should be construed as a means-plus-function claim limitation in accordance with Section 112, ¶6." (Order 26.) This Court found that the recited function includes "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." (Order 30-31.) The structure providing "a release means for retaining the guide in the charged position" according to this Court is "release lever 222," including the "latching projection 302," the "finger rest," and the "mounting section 298." (Order 33.)



(Ex. 1-D, the '797 patent, FIG. 5 (excerpted).)

This means-plus-function interpretation is proper, even though the release modifier precedes the term "means." *See Ex Parte Klumb*, 159 USPQ 694, 695 (Bd. Pat. App. & Int. 1967) (stating that expressions such as "means for printing" or "printing means" would have the same connotations); *see also Cannon Rubber Ltd. v. The First Years Inc.*, No. 03 C 4918, 2004 WL 2095669, at *4 (N.D. Ill. Sept. 17, 2004) ("It is well-settled that each word in a claim must have meaning." (citing *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1582 (Fed. Cir. 1996)).

The accused device has no structure that is even remotely similar to the release lever identified by the Court as the means for releasing and retaining the guide in a charged position nor any structure that performs both of the claimed functions. *Minks*, 546 F.3d at 1378. As described above, the release function is accomplished by depressing the Trigger Button (36), which forces the Elongated Release Bar (38) to wedge between the Latching Protrusion (48) of the Front Guide (18) and the Locking Groove (46) of the Slider Link (35).

The retaining function is accomplished when the Locking Groove (46) of the Slider Link (35) engages the Latching Protrusion (48) of the Front Guide (18) and the Guides are moved toward the proximal end of the Housing as the Crank Arm (28) is closed due to the operation of the slider-crank mechanism described on page 4 above.

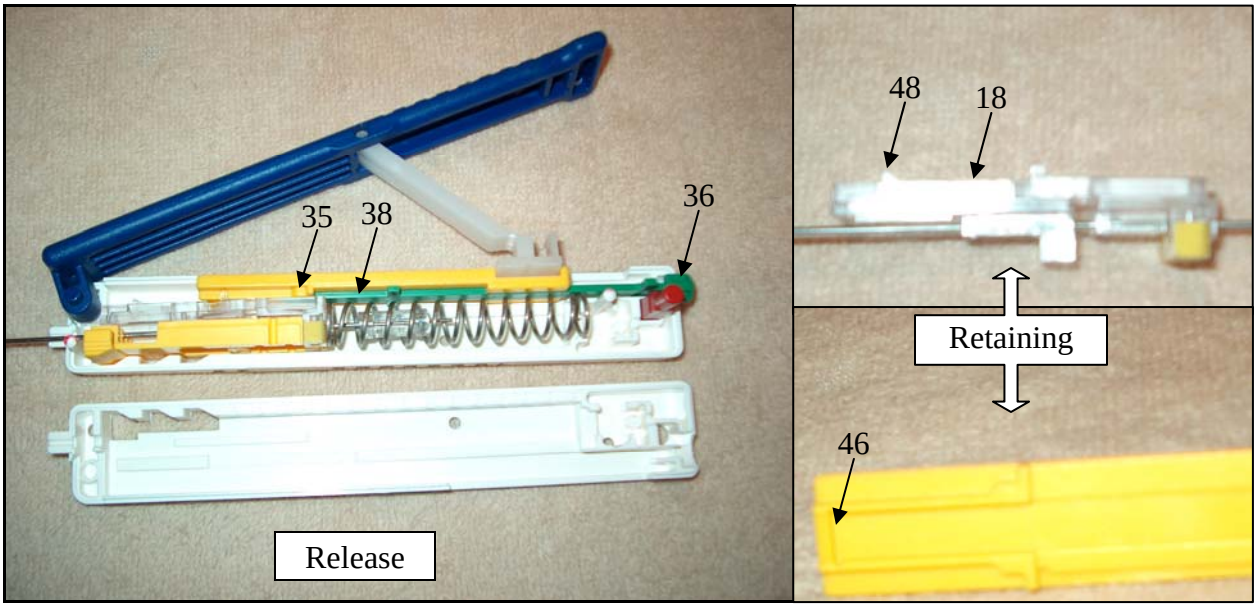
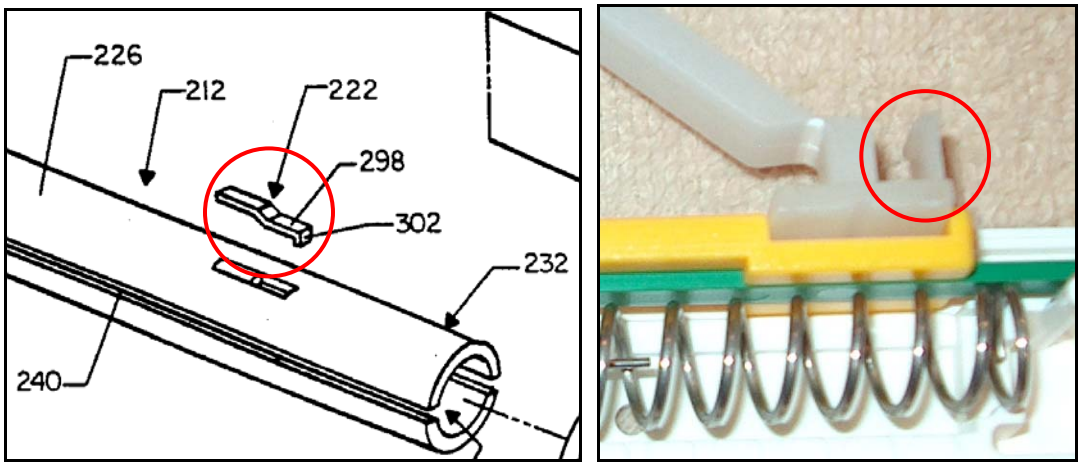


Figure 2 – The separate retain/release structures of accused device.

1. A Physician Would Not Use the Accused Device Improperly To Obtain a Biopsy Sample.

Realizing that the releasing and retaining structures of the BioPince device pictured above could never be understood as the release/lever identified by the means-plus-function

limitation of the '797 patent, Baran has suggested to Haaga that the Crank Arm Locking Tab (49) functions as a second release structure in the BioPince device. (Ex. 1-A, Haaga Dep. 205:17-206:8.) Haaga suggests that this "release" function can be accomplished by prying the Crank Arm up so that its lip disengages from the Crank Arm Locking Tab. (Ex. 1-C, Haaga Expert Report 22-23 (referring to the Crank Arm Locking Tab as a "release lever 65 that includes a latching projection 70 and mounting section 75").) Haaga admits, however, that the term "means-plus-function" is alien to his profession and that he does not understand what the term means. (Ex. 1-A, Haaga Dep. 172:15-22.) It is not surprising, therefore, that he cannot relate this structure to the "release lever" identified in the '797 patent.



(Ex. 1-D, the '797 patent, FIG. 5 (excerpted) (*left*).); Figure 3 – Close-up of the Crank Arm Locking Tab 49 of Figure 1 (*right*)

The main problem with this argument is that the Crank Arm Locking Tab is not designed to be a release and the BioPince device does not function when this method of release is used. The discharge described by Haaga as a second release means is violent and difficult to control; it causes the needle set to wobble to such a degree that it would be dangerous to perform a biopsy in this manner. Even Haaga admits that discharging the accused device by lifting the Cocking Arm is not a suitable for taking a biopsy.

Q: And you've already indicated that because of the violence with which that instrument discharges when you lift the cocking arm, it would not be suitable for use when taking a specimen, a biopsy specimen, correct?
A: Correct, in the patient.
Q: In a patient, right. In fact, when you do that, you are –
A: It would be ***very bad judgment***.

(Ex. 1-A, Haaga Dep. 204:19-205:2 (emphasis added); *see also* Ex. 3-A, Rashidi Expert Report 35-36.)

In fact, the BioPince device does not even work when this method of release is employed. When the Crank Arm is forced open on a charged BioPince device, the slider-crank mechanism remains coupled to the Guides and the extra mass creates a drag on the Guides which dampens the momentum provided by the Spring. This drag, in turn, deprives the Front Guide of the momentum necessary to separate from the Back Guide during the final stage of the discharge stroke which means that the pincer end of the Outer Tube does not move into the bore at the distal end of the cutting Cannula slicing off the tissue being sampled. (*See* Ex. 3-A, Rashidi Expert Report 15; *see also* Ex. 2, Marcoux Aff. ¶ 10.) Thus, the celebrated feature of the BioPince, the pincer, remains inoperable. (Ex. 1-G, Advertisement of the BioPince Full Core Biopsy Instrument, at MDT000008.)

A device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555-56 (Fed. Cir. 1995). Rather, the Federal Circuit instructs courts to consider the following:

(1) whether the accused infringer "intended or anticipated" that consumers would modify the accused device to operate in an infringing manner;
(2) whether consumers "actually operated" the device in an infringing manner;
(3) whether the device was "designed to be altered or assembled" before operation;

(4) whether the accused infringer's promotional materials refer to an infringing use; and
(5) whether the device "would serve any functional purpose" in its modified configuration "not already accomplished" by other configurations

Id.

There is no evidence that MDTech intended or anticipated the type of use that Haaga suggests. The marketing video depicted in Ex. 2-H, certainly does not teach such a use. As Haaga admits, none of the packaging used with the product instructs the user to operate the device in the manner Haaga describes.

Q: So there's no instruction that is given --
A: Correct.
Q: -- to the operator to pull up on the cocking arm --
A: Correct.
Q: -- of a charged BioPince, correct?
A: Correct.

(Ex. 1-A, Haaga Dep. 204:10-15). Rashidi agrees. (Ex. 1-B, Rashidi Dep. 225:24-227:1; *see also* Ex. 1-H, Instructions for Using the BioPince, at MDT004145)

There is no evidence that actual users of the BioPince device operate it in the manner described by Haaga. Haaga admits that when the device misfired because the Crank Arm did not remain attached to the Housing, physicians reported this event as a "malfunction" to the FDA and "not a proper use." (Ex. 1-A, Haaga Dep. 206:13-207:2).

Nothing in the record suggests that the BioPince was designed to be used in the manner Haaga suggests. In fact, Haaga admits that there is nothing about the design that suggests discharge by lifting the Cocking Arm of a charged device. (*Id.* 205:8-16.) He personally did not intuitively discern that the accused device could be operated in such a manner until he was told to do so by Baran. (*Id.* 205:17-206:8.) Rashidi agrees that such a function is not intended. (Ex. 1-B, Rashidi Dep. 237:14-24.)

Realizing that nothing in the record supports his strange use of the device, Haaga argues that a physician might want to disengage the Crank Arm to give a visual indication that the device is not laying on a counter in a charged state. While this is somewhat far-fetched, given that this is a disposable, single use device, there is no reason to believe that a physician who wants such a visual cue will disengage the Crank Arm while the device is in a charged state[4]. Pulling up on the arm while the device is charged requires "above average force" (Ex. 2, Marcoux Aff. ¶¶ 6-9; *see also* Ex. 1-A, Haaga Dep. 201:22-24.) The same advantages described by Haaga, visual proof that the instrument is not charged, can more easily and safely be obtained by firing the instrument properly using the Trigger Button and then lifting the handle using only average force. (Ex. 2, Marcoux Aff. ¶ 6-9.)

The accused device does not infringe under the test set out by the Federal Circuit in *High Tech* because there is no reason to use it improperly. This test applies where a claimed limitation is not present until the device is used in an infringing manner—even if the device need not be physically altered in order to infringe. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir 2005). Where the record before the court does not include evidence that such improper use occurs, summary judgment of noninfringement is proper. *Stryker Corp. v. Davol, Inc.*, 10 F. Supp. 2d 841, 844-45 (W.D. Mich. 1998) (granting summary judgment of noninfringement where plaintiff alleged defendants device could infringe without alteration if attached to a probe where there was no evidence of the existence of such a probe).

[4] The accused device does have a small window in the Housing to indicate when the instrument is charged. (Exs. 1-I, 1-J.)

2. Even if the Crank Arm Locking Tab Is a Second Release Structure, It Does Not Correspond to the Release Lever of the '797 Patent.

Both experts agree that the Crank Arm Locking Tab (49) of the accused device is not a lever, a structure identified by the Court as defining the means-plus-function limitation of claim 7 of the '797 patent. (Ex. 1-B, Rashidi Dep. 267:16-268:10.) The Crank Arm Locking Tab does not operate around a fulcrum. It is instead a cantilever, a structure fixed on one end, with no hinge, that resists flexing. (*See id.* 248:23-249:7 (explaining the operation of a cantilever).) Haaga agrees:

> **Q:** A cantilever having a secured part at the base and then your action is against -- is to pull a part back against its base, but you're not actually getting any work done on the other side of the fulcrum. You're simply moving. Isn't that what you're describing?
> [Objection to form]
> **A:** I think so, yes.
> **Q:** It is?
> **A:** That sounds like what I'm describing.
> **Q:** And with respect to -- because it's secured on an end, there's no -- it's not a lever action where you put exertion on one side of a fulcrum and get work done on the other side?
> **A:** Correct, correct.

(Ex. 1-A, Haaga Dep. 196:4-18.)

Further, Haaga admits that the Crank Arm Locking Tab does not include the finger rest identified as part of the release lever in the '797 patent

> **Q:** Okay. And with respect to the piece, number -- that you've identified as 65, that little vertical piece at the end --
> **A:** Right.
> **Q:** -- the cocking lever, cocking arm latch --
> **A:** Right.
> **Q:** -- there's no finger rest on that?
> **A:** No.

(*Id.* 187:14-21.) Rashidi agrees. (Ex. 1-B, Rashidi Dep. 267:3-4.)

Finally, the release by lifting the Cocking Arm to disengage the Cocking Arm Locking Tab does not serve the same function as the release lever of the patented invention. The structure identified as the release means for retaining the guide in a charged position allows the release function to occur in a manner that is suitable for taking a biopsy. Lifting the Cocking Arm of a charged BioPince creates a violent discharge of energy. There is no dispute in the record that it would be "bad judgment" on the part of the clinician to attempt a biopsy in this manner. (Ex. 1-B, Rashidi Dep. 233:1-15; Ex. 1-A, Haaga Dep. 204:19-205:2.)

The accused device includes separate structures for accomplishing the retain and release functions, whereas claim 7 of the '797 patent requires only one. Baran does not—and cannot—point to a single structure, not even the Crank Arm Locking Tab, in the accused device that performs identical functions to those performed by the release lever of this invention. *See Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211-12 (Fed. Cir. 1998) (stating that the accused device must perform "an identical function to the one recited in the means-plus-function clause"). The release means for retaining the guide limitation is not literally present in the accused device.

3. The Accused Device Has No Structure that Corresponds to the '797 Patent's Release/Retain Structure Even Under the Doctrine of Equivalents.

The '797 patent teaches a lever that includes a latching projection (Ex. 1-A, Haaga Dep. 177:3-8) that engages the shoulder of the guide to retain it in the charged position (*Id.*). Release is accomplished when the lever is lifted or raised off of the guide. (*Id.* 179:8-12; Ex. 1-D, the '797 patent, col. 7:66-68.) When properly used, release of the accused device is accomplished not by raising the work arm of a lever but by use of an inclined plane that wedges the Latching Protrusion 48 from the Locking Groove 46. (Ex. 3-A, Rashidi Expert Report 15.) The Trigger

Button which initiates this action and the Elongated Release Bar which performs the release are completely incapable of engaging the Guides or retaining the Guides in a charged position—let alone producing substantially the same result as the release lever of the patented invention.

Even the Crank Arm Locking Tab identified by Baran fails to meet the claim limitation under the doctrine of equivalents. As Haaga admitted, he considered structures to be equivalent if he could "look at a mechanism and if I consider this most -- the outcome of the mechanism and they do the same, the mechanism in between is maybe dissimilar, but the functionality there are the same." (Ex. 1-A, Haaga Dep 76:10-77:2.) As a result, Haaga offers no analysis to support his conclusion that the Crank Arm Locking Tab and the release lever are equivalent.

The patented invention uses a lever action to release the guide against the urging of the spring. (Ex. 1-D, the '797 patent, col. 7:66-8:4.) The accused device's Crank Arm Locking Tab is not a lever, but a cantilever. Haaga admits that to disengage the tab, the Crank Arm is pulled in a manner that causes it pull the lip out from under the tab. This would be like pushing the guide collar down and away from the latching projection of the release lever instead of lifting the lever's arm off of the collar. (Ex. 1-A, Haaga Dep. 198:15-199:3.) Thus, the structure in the accused device is not the same and does not operate in the same way as corresponding structure of the patented invention.

Finally, the patent device functions as a biopsy instrument and its release functions in a controlled enough manner to permit a user to perform a biopsy on a patient. (*Id.* col. 7:66-8:17.) This is not the case when pulling the Crank Arm away from the Crank Arm Locking Tab. These structures simply do not provide the same result.

No conclusory statements charging infringement by equivalents will satisfy the function, way, result test when comparing the patent limitation with any of the structures in the accused

device. Such hollow conclusions are insufficient to raise a triable issue of fact. *Arthur A. Collins, Inc. v. Northern Telecom, Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000) ("[I]t is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact. A party may not avoid that rule by simply framing the expert's conclusion as an assertion that a particular critical claim limitation is found in the accused device.") (internal citations omitted).

B. THE ACCUSED DEVICE USES A MECHANISM, NOT A MEMBER, TO CHARGE ITS SPRING.

This Court interpreted the claim 7 limitation, "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring," as follows: "a manually operable charging member . . . configured to move the guide to the charged position against the urging of the coil spring." (Order 26.) In deriving this definition, the Court found that "member" does not encompass "mechanism," as "'mechanism' connotes a group of ***independent*** parts working together." (*Id.* 22-23 (emphasis added).)

The accused device includes a Crank Arm that is only one part of a slider crank mechanism. (Ex. 1-B, Rashidi Dep. 259:18-260:7.); *see also* Figure 2 on page 13 of this Memorandum. Haaga admits that the '797 patent requires a member that directly charges the device:

> **Q:** So is it fair to say that your understanding of the operation of the charging member as described in the specifications of the 797 patent is that the charging member itself by virtue of its pins operates ***directly*** on the guide to pull it back against the urging of the spring?
> **A:** Correct, correct.

(Ex. 1-A, Haaga Dep. 166:25-167:6 (emphasis added).) Haaga agrees that the Crank Arm of the accused device does not operate directly against the guide.

Q: So the charging member itself is not configured to pull the guide into a charged position. It's --
A: No.

(Ex. 1-A, Haaga Dep. 169:14-16.) He further admits that the Crank Arm is part of a mechanism.

Q: So the cocking arm activates a mechanism? Is that --
A: It participates in -- it transmits its force in a dynamic process of a mechanism.
Q: Through a mechanism?
A: Right, right, right.
Q: In contrast, your understanding of the 797 patent, the charging member there is a ***direct*** force against the spring?
A: Correct, correct.

(*Id.* 171:8-17 (emphasis added).)

The Federal Circuit states that a member can be made of more than one part, but as a whole it is a firm structure. *See CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1367 (Fed. Cir. 2002) (internal quotations omitted) (holding that "member" denotes a "beam-like structure . . . such as a beam or tie, or a combination of these"). Nothing in this opinion, however, equates a multi-part member with a mechanism, and no one skilled in the relevant art would consider the terms to be synonymous. (*See* Ex. 1-B, Rashidi Dep. 77:24-80:25 and Ex. 3-A, Rashidi Report 24-26 (citing numerous authoritative texts which define mechanisms).) Nothing in the specification or prosecution history of the '797 patent overcomes the "heavy presumption" that "member" carries its ordinary meaning, so there is no genuine issue of material fact raised by the determination that a limitation calling for a "member" does not read on a "mechanism." *CCS*, 288 F.3d at 1367.

One obvious distinguishing feature between a mechanism and a member is that a mechanism provides a mechanical advantages that a member does not. (Ex. 1-B, Rashidi Dep. 197:14-19.) Here the mechanism of the accused device creates a force-amplification advantage that is not possible with the member of the patented invention's member. Haaga agrees:

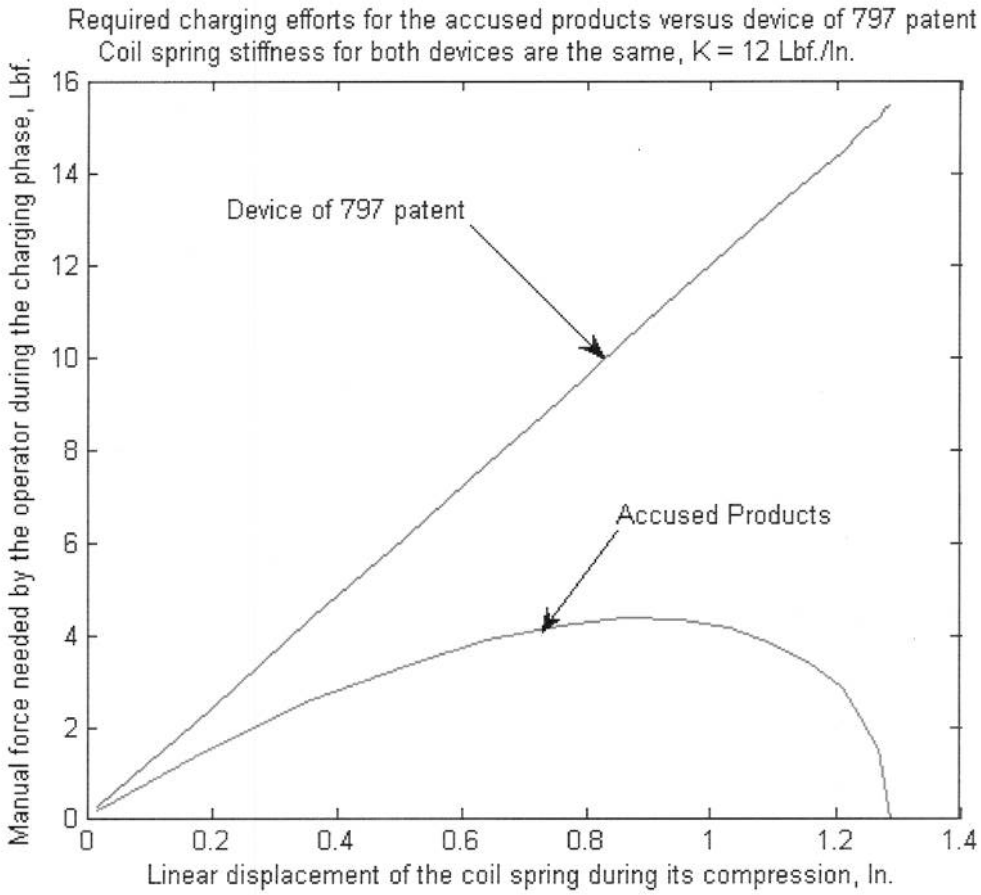
Q: In contrast, your understanding of the 797 patent, the charging member there is a direct force against the spring?
A: Correct, correct.
Q: And there's no ***multiplication*** of that force --
A: Correct.

(Ex. 1-A, Haaga Dep. 171:14-19 (emphasis added).)

Q: Further, with respect to the operation of -- to charge the BioPince device, you would agree that there is a mechanical advantage --
A: Oh, yeah.

(*Id.* 170:7-10; *see also* Ex. 1-B, Rashidi Dep. 197:14-19 (agreeing that the slider-crank mechanism of the BioPince provides "more of a mechanical advantage" than the device of the '797 patent).)

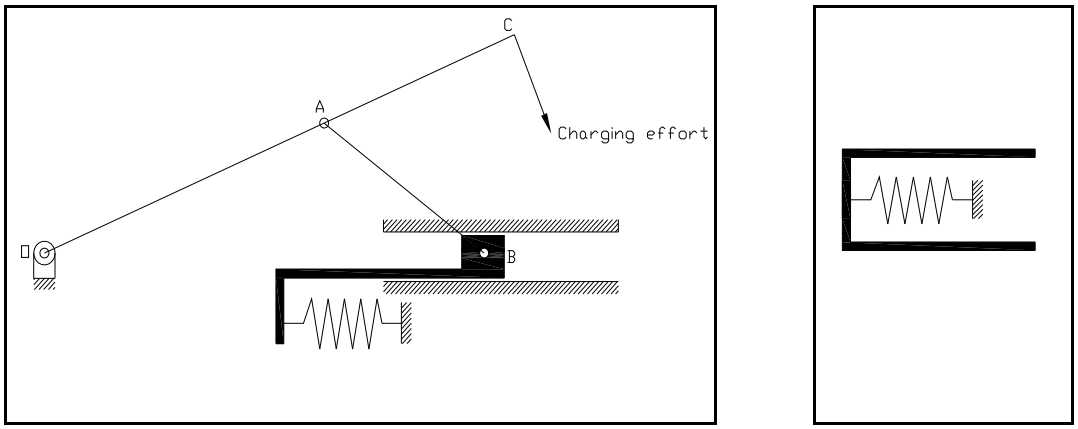
In his report, Rashidi empirically demonstrates the force-amplification advantage of the accused device's mechanism. (Ex. 3-A, Rashidi Expert Report, Exhibit 4 Figure E5, at 4-5 (including a graph demonstrating the results).) Assuming the same spring stiffness, the accused device's slider crank mechanism will always take less force to fully charge the instrument than must be used by the charging member of the device taught by the '797 patent. (*Id.* 27.)



(Ex. 3-A, Rashidi Expert Report, Exhibit 4 Figure E5 – Required manual charging forces for the accused product and that of the device according to claim 7 of the '797 patent, at 4-5.)

Regardless of the stiffness of the spring that is tested, as the spring reaches the maximum degree of compression, the Crank Arm of the slider crank mechanism becomes easier to urge against the Housing. Rashidi empirically demonstrated this on camera with the fish scale device attached to the BioPince device. (Ex. 1-B, Rashidi Dep. 262:7-264:17; *see also* Ex. 1-F, Rashidi Dep. recorded on DVD 264:18-265:25 (showing Rashidi's demonstration with the fish scale device).) Just the opposite will occur with the use of the member called for in the limitations of claim 7 of the '797 patent. The user will exert maximum force as the spring reaches the maximum compression. (Ex. 1-B, Rashidi Dep. 185:4-186:19 (explaining that with this patent's charging member, a user must use continually increasing force when squeezing the spring).)

In addition, the slider-crank mechanism changes the direction of the force used to charge the accused device. The physician will push the Crank Arm against the Housing while the slider crank mechanism causes the Guides to move to the proximal end of the Housing. Rashidi's expert report illustrates the difference in operation.



(Ex. 3-A, Rashidi Expert Report 28, 30 (Figure 3 – A schematic view of the kinematical aspects of the accused products in a ready to be charged configuration (*left*) and Figure 5 – Kinematical configuration of the charging member of the '797 patent (*right*)).)

Haaga agrees that the slider-crank mechanism changes the direction of force where the charging member of the '797 patent does not. (Ex. 1-A, Haaga Dep. 171:25-172:3.)

The only similarity between the accused device's slider crank mechanism and the member called for in the '797 patent is that they charge the springs in their respective devices. They achieve this result in entirely different ways using entirely different means. A member, regardless of its configuration, will never be able to provide the mechanical advantages of the slider crank mechanism. The dissimilarities between the charging member and the slider crank mechanism are obvious and material. The charging member limitation is simply not present in the accused device.

C. THE ACCUSED DEVICE DOES NOT INCLUDE A CANNULA MOUNT.

This Court interpreted the claim 7 limitation of "a cannula mount affixing the cannula to the guide" to mean "a structure or support which attaches or connects the cannula to the guide." (Order 19-20.) Notably, this Court concluded that the claim 7 language "contemplates and, thus, claims a piece or structure which is ***independent*** from the structures which are the guide and the cannula, and serves the function of connecting the two other structures." (Order 19 (emphasis added).)

In the accused device, there is no mount as the Cannula and the Outer Tube are bonded to their respective Guides by an adhesive. (Ex. 1-B, Rashidi Dep. 159:16-160:24 (the adhesive bonds or welds the stainless steel needles to the plastic Guides but is not itself a component or structure).) The adhesive has no independent form, uniform geometry, shape, surface area, coverage, or strength as the adhesive will simply flow over the V-shaped trough where the Cannula rests. (*Id.* 153:11-155:13.) It cannot be independently fabricated. (*Id.*) Rashidi noted that "structures are a lot more predictable in their geometry and properties." (*Id.*)

As found by Rashidi, the '797 patent requires that the mount be a pre-formed structure. This determination is appropriately influenced by several of the teachings in the '797 patent's specification. The specification is "always highly relevant to the claim construction analysis" and, as the "single best guide to the meaning of a disputed term," is usually dispositive. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Further, it is "entirely permissible and proper" to limit the claims in accordance with the specification if the specification "read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

The specification of the '797 patent describes mounts with defined structures independent of those to which they attach for both the re-useable and the single use embodiments: "The cannula mount 58, in turn, comprises a cylindrical collar 62, a conical head 64, and a cutting cannula 66" (Ex. 1-D, the '797 patent, col. 5:38-40) and "[t]he cannula mount 258 comprises a narrow base 262, a narrow cylindrical head 264 and a midsection 265 . . . ." (Ex. 1-D, the '797 patent col. 9:26-27).

Haaga, on the other hand, identifies the hardened adhesive as the "cannula mount" because he believes that it has a "firm consistency" and is "hard" in its final form. (Ex. 1-A, Haaga Dep. 122:2-123:25.) He fails, however, to distinguish between the verb, "mount" and the noun that is called for in the claim limitations. Haaga's conclusion is wrong and it fails to create a triable issue of fact because, even he admits that his conclusion does not make sense in light of the teachings of the '797 patent.

The '797 patent teaches that in the single use device, a cannula mount can be adhesively bonded to a bore of the guide:

> The base 262, the head 264, and the midsection 265 are axially bored to receive the cutting cannula 266, which may there be secured by means of adhesive (not shown) . . . .

(Ex. 1-D, the '797 patent col. 9:28-31.)

Haaga could not explain how the patent could be teaching the application of adhesive to adhere the cannula to a mount comprised of adhesive which in turn is connected to the guide by adhesive. (Ex. 1-A, Haaga Dep. 144:2-11.) Any suggestion that the cannula mount could also be an adhesive, therefore, conflicts directly with the teachings of the '797 patent and renders these teachings of the specification meaningless. The conclusions expressed by Rashidi, on the other hand do not do violence to the language of the patent.

The limitation of a cannula mount is not present in the accused device either literally or under the doctrine of equivalents. The accused device simply does not have such a structure, but instead relies on a physiochemical reaction to bond or weld the cannula to its Guide. (Ex. 1-B, Rashidi Dep. 160:12-24.)

IV. CONCLUSION

The experts fundamentally agree on the material facts. Admissions made by Haaga, the Plaintiff's expert, undercut his conclusions with respect to infringement. His failure to demonstrate the precise correlation between the elements he calls out of the accused device and the claim limitations of the '797 patent further renders many of his conclusions legally meaningless. Rashidi, on the other hand, provides empirical evidence to support his assertions that the limitations of claim 7 of the '797 patent read on the BioPince. For these reasons, this Court should grant MDTech's summary judgment of noninfringement.

Certification as to page limits: This matter has been assigned to the Standard Track and this Memorandum in Support does not exceed 30 countable pages, as required by this Court's Case Management Plan, Docket Entry No. 25, at ¶ 14.

Dated: December 22, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2008, a copy of foregoing **MEMORANDUM IN SUPPORT OF DEFENDANT MEDICAL DEVICE TECHNOLOGIES, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT** was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's system.

Dated: December 22, 2008

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